DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region m2415n

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

Telephone (973)

WARNING LETTER

Certified Mail
Return Receipt Requested

File # 99-NWJ-16

February 25, 1999

Mr. Richard H. Byma
Owner
By-Acres Farm
601 Route 519
Sussex, NJ 07461

Dear Mr. Byma:

An investigation at your dairy operation located in Sussex, New Jersey, conducted by FDA's New Jersey District on 1/20 and 1/25/98, confirmed that you offered animals for sale for slaughter as food in violation of Sections 402(a)(2)(C)(ii) and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act), and you may have caused animal drugs to become adulterated within the meaning of Section 501(a)(5) of the Act.

On 7/7/98 and 8/4/98 you sold two bovine animals, identified as tag 5929 and 6296 respectively, for slaughter as human food to [redacted]. The animals were then sold by [redacted] and transported to their facility. USDA analysis of kidney tissue samples collected from the animals in question identified the presence of 0.86 ppm Gentamicin Sulfate for tag 5929 and 3.20 ppm Streptomycin for tag 6296. No tolerance for Gentamicin Sulfate residues has been established for bovine tissue, per Title 21, Code of Federal Regulations, Part 556.300. Its presence in bovine tissue therefore causes the food to be adulterated. Further, the tolerance for Streptomycin residues in bovine kidney tissue is 2.0 ppm. The levels identified in the bovine tissue exceeded the tolerance and the edible tissue is therefore adulterated within the meaning of 402 (a)(2)(C)(ii) of the Act.

Our investigation found that you hold animals under conditions inadequate to prevent diseased and / or medicated animals bearing potentially harmful drug residues from entering the food supply. For example, you lack an adequate system for assuring that animals have been treated only with drugs that have been approved for use in those species. The Gentamicin Sulfate product, with which you treated the animal in question (tag 5929), is not approved for use in

bovine animals. Additionally, you did not withhold the animal in question (tag 6296) from slaughter for the required time to permit depletion of any potentially hazardous residue of Streptomycin from edible tissue. Finally, you did not maintain a system of medication and treatment records that, at a minimum, identify the treated animals, dates of treatment, drugs administered, persons administering the drugs, and the withdrawal time required prior to slaughter.

Our investigation showed that you adulterated the drugs Gentamicin Sulfate and Streptomycin that you used to treat the animals in question within the meaning of 501(a)(5) of the Act when you failed to use the drugs in conformance with their approved labeling. Your use of Gentamicin Sulfate in a species for which it is not approved and your failure to allow the labeled withdrawal period for Streptomycin caused the drugs to be unsafe for use.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operation and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and /or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing within fifteen (15) working days of receipt of this letter, indicating the steps you have taken to bring your firm into compliance with the law. Your response should include each step that is being taken, has been taken, or will be taken to correct the violations and prevent their recurrence. If corrective action cannot be completed within fifteen working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made. Your reply should be directed to the Food and Drug Administration, Attention: Erin D. McCaffery, Acting Compliance Officer, at the address and telephone number above.

Sincerely yours,

Douglas I. Ellsworth
District Director